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Ranking Minority Member
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
U.S. House of Representatives
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Hearing on "RU-486: A Low Standard for Women's Health?"

May 17, 2006

Mr. Chairman,

I want to join you in welcoming all of our witnesses testifying this afternoon on a very important subject: protecting women's health.

In particular, I want to acknowledge Mr. Monty Patterson who lost his 18-year-old daughter, Holly, when she died as the result of a rare bacterial infection. I offer my sincere condolences to the Patterson family and want to commend Mr. Patterson for his efforts to become well-versed in this subject area in the wake of a terrible family tragedy.

As you know, Mr. Chairman, *C. Sordellii* ("Cee sore-DELL-ee-eye") is a bacterium that normally resides in soil. Although cases of human illness are rare, the effect is usually fatal when the bacteria produce toxins that cause rapid onset of shock that physicians are powerless to curtail.

To date, the medical literature reflects a total of approximately 30 reported fatalities from *C. sordellii* infection. Cases of infection have involved both males and females of all ages.

At least eight of the reported fatalities occurred in women who had just given birth, and two occurred after miscarriages.

The selective focus of today's hearing centers on five fatal cases that have occurred over the past five years and also involved pregnancy. Four of these cases occurred in California, the other in Canada. The key factor linking this small subset of cases is that they occurred in women who underwent medical abortion.

Last week, the Centers for Disease Control convened a scientific meeting on *C. sordellii* and another, related bacterium. The meeting served to underscore just how little is known about the cause of human *C. sordellii* infections. Although a number of theories were advanced and debated, the meeting produced no solid answers as to how the infection is acquired. The only consensus was that much more needs to be learned if additional deaths are to be prevented.

Despite the overwhelming scientific uncertainty among experts, a number of policy makers and policy shapers apparently have already arrived at the conclusion that the drug mifepristone ("miff-eh-PRISS-tone") -- also known as "RU-486" and marketed in the United States under the name Mifeprex ("MIFF-eh-prex") -- is the likely cause of the infection in the five cases involving patients who underwent medical abortion. Consequently, they are advocating the FDA's immediate withdrawal of Mifeprex from the market.

What is the basis for this belief? Is it science? Or is it something else?

It is difficult to overlook the fact that adherents to this point of view generally opposed the introduction of mifepristone into the United States in the first place -- or to ignore the fact that they did so on ideological grounds, knowing that there had been no reported fatalities among as many as 2 million users of the drug in Europe.

To bolster their argument, proponents of withdrawing FDA approval suggest that the FDA in effect rushed the drug to market; but the record shows that the approval process was thorough and unusually lengthy. Moreover, it resulted in more stringent restrictions on distribution than apply to most other drugs.

Mr. Chairman, I hope it is fair and correct to presume that not one participant in today's hearing takes the health of women lightly. My own concern for both women's health and women's rights leads me to wonder, however: why the narrow focus on these cases, and on this drug as the suspected culprit? Why not concern ourselves with all of the possible causes of infection in not only these five cases, but also the other nine or ten reported cases in which pregnancy was the common denominator?

If ensuring a high standard of health care for American women is our pure objective, it just seems to me, Mr. Chairman, that our focus should be seeking the truth concerning the cause of *C. sordellii* infection, rather than attempting to bully the FDA into taking action, unsupported by science, that would have just one certain impact: limiting access to abortion for many, many women.

Therefore, I hope today's hearing can serve the purpose of promoting *thorough* scientific inquiry and supporting a *research agenda* that will lead us to answers that can prevent infection and death from infection.

Concentrating on five cases involving medical abortion, to the exclusion of a larger number of equally tragic cases, appears to serve the narrower purpose of whittling away at a woman's constitutional right to choose, by limiting practical access to abortion. I only hope that, in this case, appearances are deceiving.

I look forward to the testimony of our witnesses and yield back my remaining time.

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